510(k) SUMMARY

Infinite Biomedical Technologies' I-2000 Monitor K072382

Infinite Biomedical Technologies, LLC
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Baltimore, MD 21211

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Contact Person: Manan Hathi
Date Prepared: 21 January 2008

Name of Device and Name/Address of Sponsor

Model I-2000 Monitor

Infinite Biomedical Technologies, LLC
3600 Clipper Mill Road, Suite 410
Baltimore, MD 21211

Common or Usual Name

Electroencephalograph

Classification Name

Electroencephalograph (CFR 882.1400, Class II)

Predicate Devices

BrainZ Instruments Ltd. - BRM2 Brain Monitor (K030489)

Excel Tech Ltd. – Xltek EMU40 EEG Headbox (K053386)

Intended Use / Indications for Use

The I-2000 Monitor is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the head.

The I-2000 Monitor is indicated for use in monitoring the state of the brain by acquisition of electroencephalogram (EEG) signals, in research and clinical environments.

Technological Characteristics

The I-2000 Monitor is a two-channel EEG monitor and consists of a tablet PC, battery powered wireless headbox, headbox charger, and power conditioner integrated into a mobile console. The tablet PC provides processing, display, and storage of EEG signals.

User operation of the Monitor is accomplished using the graphical user interface and touch screen tablet PC. The signal display formats are EEG waveforms, EEG power spectrum, and 95% Spectral Edge Frequency. Various amplitude display scales are available and event marking capability is provided. The screen is adjustable for user comfort.

The power spectrum will be displayed as a line graph for each of the four frequency bands traditionally used to quantify EEG signals [Delta (0-4 Hz), Theta (4-8Hz), Alpha (8-13Hz) and Beta (13-30 Hz)] over time. The 95% spectral edge frequency is the frequency below which 95% of the total EEG power is concentrated. This is also displayed as a line graph over time.

The headbox provides amplification, digitization, and transmission of EEG signals. Wireless Bluetooth communication provides complete electrical isolation of the patient from the monitor. The headbox is recharged in a custom charger within the console when not being used for monitoring.

EEG signal processing includes data checking for artifact and electrode contact impedance. Stored EEG signals may be exported to removable storage.

The integrated console features a stable base with 6 casters and a power conditioner to provide an additional protection barrier for both users and patients.

Performance Data

Laboratory testing demonstrated that the I-2000 Monitor meets its design and functional requirements. Actual device functions and features were evaluated against the device specifications and in all instances the I-2000 Monitor performed as expected and no unexpected behavior was observed. The device meets the requirements of UL medical electrical equipment standards for safety and the IEC particular standard for electroencephalographs.

Substantial Equivalence

The I-2000 Monitor is as safe and effective as the BrainZ BRM2 Brain Monitor and the Xltek EMU40 EEG Headbox. The I-2000 Monitor has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the I-2000 Monitor and its predicate devices raise no new issues of safety or effectiveness. Thus, the I-2000 Monitor is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Infinite Biomedical Technologies
c/o Mr. Manan Hathi
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Baltimore, MD 21211

APR - 9 2012

Re: K072382
Trade/Device Name: Model I-2000 Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, OMC
Dated (Date on orig SE ltr): January 29, 2008
Received (Date on orig SE ltr): January 29, 2008

Dear Mr. Hathi:

This letter corrects our substantially equivalent letter of February 15, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072382

Device Name: Model I-2000 Monitor

Indications for Use:

The **I – 2000 Monitor** is an electroencephalograph as per CFR §882.1400. It is used to measure and record the electrical activity of a patient's brain, obtained by placing electrodes on the head.

The **I-2000 Monitor** is intended to monitor the state of the brain by acquisition of electroencephalogram (EEG) signals, in research and clinical environments.

Prescription Use __X__ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Page 1 of 1

Division of General, Restorative, and Neurological Devices

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